

Evaluation of a Motion-Activated Refusal-Skills Training Video Game for Prevention of Substance Use Disorder Relapse

Date: November 10, 2015

3. ABSTRACT OF RESEARCH PLAN

Appendix B

ABSTRACT OF RESEARCH PLAN

NAME, ADDRESS, AND TELEPHONE NUMBER OF OFFEROR ORGANIZATION Media Rez LLC 1325 Corcoran St NW, Washington DC 20009 202-483-9411	AGENCY NAME: National Institute on Drug Abuse SOLICITATION NUMBER: N44DA-14-4419 TOPIC NUMBER: 150
---	---

TITLE OF PROJECT
Relapse Prevention Motion and Voice Video Game

KEY PERSONNEL ENGAGED ON PROJECT

Name (First, Middle, Last)	POSITION TITLE	ORGANIZATION
Daniel Greenberg	Principal Investigator	Media Rez LLC
Dr Lorien Abrams	Co-Investigator	George Washington University
Dr Marc Fishman	Co-Investigator	Mountain Manor Treatment Center

ABSTRACT OR RESEARCH PLAN: State the proposal's long-term objectives and specific aims, making reference to the health-relatedness of the project. Describe concisely the research design and methods for achieving these goals, and discuss the potential of the research for technological innovation. Summarize the results that are expected. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the proposal is funded, this description, as is, will become public information. **Therefore, do not include proprietary/confidential information. DO NOT EXCEED 200 WORDS.**

This project proposes to continue the development of an intervention for relapse prevention in the form of a professional quality video game which rewards drug-rejecting physical motions and spoken refusal phrases. Phase I research findings showed that youths in recovery experienced increased low craving levels, strong levels of satisfaction, and interest in attending treatment sessions where the intervention is available—an important outcome since failure to attend treatment is highly correlated with relapse. In Phase II we propose to modify and expand the prototype based on customer feedback from treatment centers, counselors, and patients. We will test the effectiveness of the motion and voice controlled game in a randomized controlled trial of youths in treatment for opioid use disorder who have access to the game for a month. We will measure the effect of gameplay on successful completion of detoxification/inpatient treatment and rates of linkage to next level of outpatient treatment. We will also measure the effect of game play compared to treatment as usual during a subsequent episode of outpatient treatment (following inpatient), on rates of treatment attendance, treatment retention, urine drug test results, substance use self-report, treatment alliance, drug craving, and treatment satisfaction.

Provide key words (8 maximum) to identify the research or technology.
drug abuse relapse prevention recovery videogame motion voice

Provide a brief summary of the potential commercial applications of the research.
Treatment centers need resources for reducing cravings and motivating youths to return to the challenging work of recovery. Adding play through a professionally-developed motion and voice video game allows patients to rehearse spoken refusal skills and drug-rejecting physical actions in a fun and rewarding

4. RESULTS OF PHASE I EFFORT

“It made me feel good about my recovery.” - Participant

The goal of Phase I was to demonstrate the feasibility of developing a commercial prototype of an affordable, off-the-shelf, body-motion activated game for relapse prevention and opioid recovery using state-of-the-art software development from a proven video game industry production team and tested by experts in addiction and treatment. All project aims were accomplished. We found strong levels of satisfaction and low craving levels. The majority of patients were very interested in playing the full version as part of their treatment and said it would make them more likely to attend treatment sessions. (See Phase 1 Final Report in Appendix for more information.) Four project aims were carried out:

Aim 1: Concept Testing (Month 1): Elicited qualitative feedback from young people in recovery, in a focus group format on the concept of Recovery Warrior and the proposed design features of Recovery Warrior (e.g. levels, motion actions, settings, point system, depiction of opiates). We found high interest in the game. All the participants wanted to play a recovery game for relapse prevention, including the participants without much interest in video games. 83% said they would be more interested in going to group if the game was available, and fully 50% said they would “definitely” attend more.

Aim #2. Prototype Development (Months 2-4): Developed the Recovery Warrior prototype 1.0 based on feedback from Aim #1. The technical team integrated the preferred locations, art style, locations, gameplay types, etc. The team exceeded the specification for a complete gameplay form by building two, Recovery Ninja and Recovery Runner. Voice commands were integrated so players could benefit in the game when they spoke refusal phrases. All game-breaking bugs were eliminated.

Aim #3. Pilot Study--Feasibility and User Interface Testing (Months 5): Conducted a test of the Recovery Warrior 1.0 prototype with adolescents in recovery (n=9) to assess user interface performance. Qualitative feedback was obtained from young people who played the game in a single session. When asked about their interest in the prototype, 100% reported that our game would make them more interested in attending their group treatment sessions at MMTC. The 1.0 prototype was revised according to feedback into the 2.0 prototype.

Aim #4. Formative Evaluation-Acceptability, Impact on Outcomes (Month 6): Conducted a formative evaluation of the Recovery Warrior 2.0 prototype with young people in recovery (n=9) to assess the impact of the program on satisfaction with the service and on relapse-related outcomes. After the first session of gameplay (Week 1), participants reported a high level of agreement that if video game play was offered as part of their treatment they would be more likely to make it to more treatment sessions. They also agreed that they would be less resistant to going to treatment knowing that the video game was there for them to play. Participants reported a high level of interest in playing the video game as part of treatment. Participants agreed that they would recommend the video game to other people in treatment. Satisfaction was sustained in most cases after game play in Week 2. Participants did not feel that playing the video game initiated cravings or intensified their craving level. Participants reported experiencing less than a slight/mild urge to use during game play. Reflecting on feelings experienced during gameplay, most participants reported feeling empowered, hopeful, intelligent and happy. Other commonly reported emotions included feeling energetic, optimistic and strong.

In Phase I we were able to produce a substantial amount of innovative, effective, satisfying and state-of-the-art video game content on a very modest budget. Prototypes in the games for health space are often perceived as sub-standard when compared to commercial games because they are rarely produced by professional game developers with extensive experience in making commercial video games, and they rarely are developed following video game industry best practices, even when they have sizeable budgets. We expect to be able to provide the NIH with a high value return on the SBIR funds in Phase II. We demonstrated feasibility though high acceptability, strong interest in returning to treatment, improved positive feelings, and high professional video game quality.

5. RESEARCH PLAN FOR PHASE II PERFORMANCE : STATEMENT OF WORK

Appendix E: (Statement of Work does not contain proprietary material)

Title: Relapse Prevention Motion and Voice Video Game

I. Background Information and Objectives

A. Background Information

Opioid dependence is a growing problem among adolescents, with high rates of relapse and treatment dropout. Improving treatment with new technology holds great promise, but past attempts at therapeutic video games weren't compelling to adolescents because they didn't involve best-practices from the game industry, or used prohibitively expensive technology. The Contractor will develop a game targeting opioids, in which adolescents battle drugs using affordable, off-the-shelf, body-motion and voice activated game console hardware and state-of-the-art design from a proven game industry production team. The Contractor will develop and iteratively test a game that adolescents will want to play because it is fun, incorporating theory-driven therapeutic content targeting factors known to improve treatment outcomes. The Contractor will: 1) Develop the game, test it multiple times with both recovering adolescents receiving treatment and substance abuse counselors, and revise it accordingly based on multiple rounds of feedback from patients and counselors, 2) develop and implement a plan for using the game as a therapeutic tool within a treatment program, and 3) test the efficacy of the Recovery Warrior game in a pilot randomized controlled trial. Outcome variables will include a) the mediators of addiction recovery, b) treatment adherence, and c) clinical relapse outcomes. Participants will be interviewed at the time of enrollment and followed up in-person or by phone at 2 weeks, 4 weeks, and at 3 months post enrollment.

B. Phase II Technical Objectives

B.1. Specific Objectives: The first phase of the study will be aimed at refining the prototype, the second at developing a protocol for integrating the prototype into treatment, and the third at conducting an efficacy trial of Recovery Warrior compared to treatment as usual.

Aim 1. Commercial game development.

To expand and refine the Recovery Warrior game prototype developed in Phase I into a full commercial style game based on feedback from youth in treatment and counselors.

- a. Develop the creative content and complete programming of the game to achieve 6-8 hours of total game play within several modes of play (Recovery Ninja, Recovery Runner, Recovery Volleyball, etc.), multiple levels, multiple avatars, and enhanced voice-activated response etc.
- b. Iteratively test and refine the game using four focus groups of 4-8 youth in SUD treatment and 3-5 counselors to inform the ongoing programming and game development
- c. Test and debug the finished game

Aim 2. Game Integration into Treatment.

To develop and implement a plan for using the game as a therapeutic tool within a treatment program

- a. Write a counselor's manual for game facilitation in a treatment setting
- b. Solicit input from counselors about the use of the game as a therapeutic tool manual (n=5 individual interviews).
- c. Test the feasibility and acceptability of implementing the game through a small uncontrolled pilot (n=10) within the inpatient and outpatient treatment program

Aim 3. To test the efficacy of the Recovery Warrior game in a pilot randomized controlled trial

- a. Enroll 100 youth with opiate addiction in short-term inpatient treatment and randomize to Recovery Warrior game play plus Treatment As Usual (n=50) or Treatment As Usual (TAU) (n=50). For those randomized to game play, provide daily game play during inpatient treatment (1-2 weeks) and weekly game play for 4 subsequent weeks during outpatient care.
- b. Examine the effects of game play on 1) the mediators of addiction recovery, 2) treatment adherence, and 3) clinical relapse outcomes. Participants will be interviewed at the time of enrollment and followed up in-person or by phone at 2 weeks, 4 weeks, and at 3 months post enrollment. Additionally, participants will receive brief assessments at all sessions of game play they attend.

B.2 Anticipated End Results:

To determine feasibility, these are the research questions we will seek to answer from our evaluation of the prototype. The formative evaluation includes the following hypotheses:

Hypothesis 1: Participants who receive Recovery Warrior 2.0 will report greater improvements in the mediators of addiction recovery (e.g. reduced cravings, greater improvements in refusal self-efficacy,) compared to those in usual care.

Hypothesis 2: Participants who receive Recovery Warrior 2.0 will have increased treatment retention and adherence at Mountain Manor (e.g. higher rates of inpatient completion, higher rates of linkage to outpatient care, better improvements in attendance in outpatient treatment, higher levels of counselor and treatment alliance, and lower drop-out rates) compared to those in usual care.

Hypothesis 3: Participants who receive Recovery Warrior 2.0 will have better positive outcomes on clinical relapse measures (e.g. self-report of drug use, urine drug screens) compared with those in treatment as usual.

II. Services to be Performed

A. General Requirements

1. The Contractor shall independently, and not as an agent of the Government, perform all work and furnish all labor, materials, supplies, equipment, and services (except as otherwise specified in the contract) to develop the Phase II Recovery Warrior Motion and Voice game for relapse prevention and test it with young people in recovery.

2. The Contracting Officer's Representative (COR) in Section G the contract will monitor the work.

B. Specific Requirements

Below are the tasks with parameters for the project, objectives, end products and deliverables, and the reports required to monitor work progress under the contract.

B.1 Work Plan for Aim #1: Commercial Game Development

Overview of Aim #1

Goal: To modify the Recovery Warrior prototype developed in Phase I in response to feedback from both our customers (treatment center counselors) and our end users (adolescents and young adults in

recovery). We plan to elicit qualitative feedback from counselors and patients in recovery on a quarterly basis starting in the third month after the start of the Year 1 of Phase II. The software design, programming, animation, sound effects, and other game elements will subsequently be revised by the technical team based on the results of each focus group, under the direction of PI Greenberg. This work will be conducted primarily at the offices of Media Rez, with some work at telecommuting offices of technical personnel. (All work will be done in the United States.) The focus group questions will be created with the assistance of Dr. Abroms and Dr. Fishman. The objective of this year-long iterative feedback process is the creation of a professional quality relapse prevention video game product that scores high levels of acceptability with both counselors and patients. After a year of development, the product will be ready for an RCT Pilot clinical study evaluating the effectiveness of the newly developed motion and voice video game.

Participants: We will recruit counselors from Mountain Manor Treatment Center (MMTC) four times during year 1. These four groups consist of three to five counselors (3-5), and they will review the progress of the product during the first year of development. We will recruit a group once each quarter during the first year, starting the third month of Year 1 (after IRB approval). We will also recruit a group of four to eight (4-8) adolescents and young adults in the youth opioid treatment program at MMTC four times a year during the first year, starting in the third month of Year 1 (after IRB approval). They will also review the game in progress. MMTC staff will announce the availability of the study, and those that express interest will be approached by the study RA to obtain consent/assent (and parental consent for those <18). At these quarterly reviews, we will perform a design review, showing sample art, animation, level design, and the prototype in development. We will solicit feedback and ask how the improvements reflect the feedback they gave in the previous month. We will ask for new ideas and approaches to gameplay. These sessions will be held at Mountain Manor Treatment Center in Baltimore, MD, as will all feedback and focus group sessions.

B.1.1. Work plan

An in-depth understanding of the target audience is key to the success of any behavioral intervention. Feedback from adolescents and young adults in recovery is essential for identifying the needs and concerns of this group so that the game can be designed to meet those needs. Therefore, we will use both questionnaires and focus groups to gain an understanding of the needs and perceptions of both counselors and patients.

B.1.2 Counselors

We will survey 3-5 counselors four times during the first year of software production, once per quarter starting in the third month of Year 1. The goal of these focus group discussions is to gain an understanding of the needs and perceptions of adolescents and young adults in recovery from opioid addiction and to elicit from reactions to the proposed concepts and development of Recovery Warrior. We will seek feedback on the core gameplay of Recovery Warrior and the proposed design features (e.g. levels, motion actions, settings, point system, depiction of opiates, etc.). Each session will last approximately 60 minutes. The first of four sessions in year 1 will be principally concerned with design goals and incorporating best practices of treatment. The second session will focus on implementing features. The third session will focus on improving level design. The fourth sessions in year 1 will focus on polish and player engagement. The questions they will be asked will be different in each session, with no questions repeated from earlier sessions.

B.1.3 Adolescents and Young Adults in Recovery

We will survey 4-5 adolescents and young adults in recovery four times during the first year of software production, once per quarter. The research process will consist of focus groups to gain an understanding of the needs and perceptions of adolescents and young adults in recovery from opioid addiction and to

elicit reactions to the proposed concepts and development of Recovery Warrior. Each session will last approximately 60 minutes, and will ask different questions from other sessions.

The focus group will cover the following topics: 1) assess current recovery and plans for avoiding relapse, 2) assess needs and motivations for preventing relapse based on constructs from the Social Cognitive Theory (e.g. outcome expectations associated with remaining abstinent, sources of social support, self-efficacy, behavioral capability, and observational learning), 3) get feedback on the Recovery Warrior intervention prototype, including reaction to the design and gameplay elements and proposed new features and animation, and 4) assess the perceived value of the motions used in the game and the potential refusal phrases that the player can speak during gameplay for higher scores and better performance against the “attacking” drugs in the game.

Participants will be shown the Recovery Warrior game in progress and given an opportunity to play so they can experience it first-hand. Then they will answer questions about levels, motion actions, settings, the point system, solo play / cooperative team play, depiction of opiates, art style (realistic and stylized), and sample refusal phrases. (Samples: “I don’t use drugs,” “I’m clean.”) We will assess what players feel would be most satisfying in seeing their onscreen character attack or evade drugs. We will ask the participants about how interesting and engaging they find the in-game activities, how challenging they find the level progression, how rewarding they find the scoring, how appealing they find the onscreen characters, how polished and professional the game looks, feels, and plays, and most importantly, how fun the game is.

The sample will be stratified in order to reflect the prevalence of opioid use across genders and racial/ethnic groups. Because of the geography of Baltimore, MD, DC it is not expected that it will be possible to recruit subjects of American Indian ancestry. This is a limitation of the current study that can be addressed by a future study that focuses on drug recovery in this population. Nonetheless, an effort will be made to insure that there is appropriate representation in the sample among Whites, African-Americans, and Hispanics. Subjects will be recruited from Mountain Manor Treatment Center in Baltimore, supervised by Dr. Fishman and his site coordinator, Dr. Hoa Vo. After they agree to participate they will be sent reminders. The session will be scheduled after a standard treatment group meeting to facilitate their participation (so they do not have to make a second trip to MMTC in order to participate in the focus group). Participants will be reimbursed for their time with a gift card for \$20. This focus group format worked well in Phase I, and resulted in invaluable feedback that greatly increased the game’s acceptability and perceived value to the adolescents and young adults in recovery.

B.1.4 Procedure for Data Collection and Analysis of Results from Interviews

Responses will be entered into a database and themes analyzed. The analysis of the interviews will inform the further development and revision of the Recovery Warrior prototype. Based on the results of the concept testing, decisions will be made about content areas to focus on and how best to depict the player’s avatar, the drugs, and the gameplay. Key decision areas will include: which types of attacks on and evasions of drugs generate the most interest, how best to appropriately depict the dangers of each drug type (and possibly drug combinations), art and animation style, settings, etc. The technical team will revise the design document accordingly and then the programming and graphics departments will implement the prototype.

B.1.5 Procedure for Phase II Prototype Development

After each focus group session, the Design Document will be updated to reflect the feedback of counselors and patients. The design document serves as a blueprint to build the game. We will follow it to incorporate the elements preferred by our customers and eliminate material that does not measure up, revising types of gameplay, art, animation, backgrounds, settings; visual style and actions of the drugs and dealers to convey menace; two-player cooperative vs. competitive play, levels, refusal phrases, etc.

The software development team will then create the game programming in the Unity 3D software creation “middleware” engine to support the prototype.

This prototype development process will take the first year of Phase II. At the end of Year 1, the Phase II prototype will be feature-locked and delivered to MMTC for Aim 3 testing. Software development work will continue on the final release version of the product, but at a reduced pace, and will not affect the version undergoing testing in Aim 3.

B.2 Work Plan for Aim #2: Game Integration into Treatment

Overview of Aim #2

Goal: The Recovery Warrior game is intended to be a therapeutic tool that synergistically augments other current treatment modalities. While it may later gain traction as a direct to consumer product, our initial conception of the game’s efficacy, adoption, dissemination and sustainable commercial success is as a therapeutic tool embedded within existing treatment programs for youth. Our theoretical model, as shown in Figure 2 (B.4 Theoretical Basis of Recovery Warrior, below), predicts that 1) playing the game will increase treatment engagement by making treatment more fun and participatory, and 2) the game play treatment and treatment as usual will synergistically reinforce each other in terms of the messages and skills learned in each setting. Thus, it will be important to develop a counselor protocol for implementing the game play which optimizes the synergy between treatments.

Elements of treatment integration and counselor facilitation will include: comfort, competence and “ownership” of the game by counselors as a therapeutic tool; logistics of incorporation of the game into the agenda and flow of treatment (dose, timing, schedule etc.); the counselor role as enthusiast and cheerleader for the game; the counselor role as manager of game play (managing the equipment, facilitating turn taking and fair play, managing the right balance of rowdiness and order, ensuring safety etc.); the counselor role as debriefing and processing the content of the game as it relates to recovery and treatment messages. The facilitation of the game by counselors and the incorporation of the game into treatment will be the focus of this Aim, to include documentation in a counselor manual, incorporation of counselor feedback into the process in general and the manual in particular, and the small-scale pilot testing of the game intervention in the treatment center as a dress rehearsal for the RCT in Aim 3.

B.2.1 Work plan for Aim 2a – counselor training manual

As the game undergoes further development by the technical team, the clinical team led by Dr. Fishman will draft the counselor facilitation manual. This will be the introduction to the game for professionals, and the training guide for implementation of the game as a therapeutic tool within a treatment context. The manual will contain material on the background, rationale and purposes of the game. It will be particularly important to place the game intervention in the more familiar context of other experiential therapeutic activities, which will help prevent its being initially trivialized or rejected as “just a game...” It will need to help counselors be comfortable with the use of a game as a non-trivial tool having serious benefits despite seeming at first to be more aimed at “fun” than “recovery”. It will contain some user’s manual material for technical guidance on how to use the game, both hardware and software, for counselors who might not themselves be familiar with video games and gaming systems.

Most importantly, the manual will describe our model of how counselors can incorporate the game into treatment as an augmentation to their usual treatment components, in a way that dovetails easily with any current treatment approach without having to change anything fundamental about TAU, as a kind of “snap-on” tool to make treatment more effective and fun.

The following are a partial list of examples of the topics that will be covered in the manual:

- The importance of mastery of refusal skills in addiction recovery
- How counselors can energize patients through physical activation, increasing their levels of arousal, making them more enthusiastic in their motivation and “fired up” towards the goals of treatment
- How counselors can manage and direct the energy of the individual and/or group to keep the focus on recovery content and goals, and to prevent over-exuberance from becoming chaotic or disruptive
- Utilizing counselor facilitation to debrief and process the thoughts and feelings elicited by game play, draw analogies between various contents of game play and their own real-life experiences:
 - How are the refusal skills rehearsed in the game similar or dissimilar to refusal skills in real life?
 - How can refusal vocalizations be utilized in real life?
 - How does it feel to be assertive about drug refusal?
 - What if refusal statements and actions make you feel “stupid” or “lame” or rejected by peers?
 - What can you do in treatment when discussion or images of drugs make you excited with positive nostalgia, or even provoke cravings? Or in real-life? How can you use urge-surfing, deliberate unmasking, asking for help, and other techniques as an antidote to craving?
 - How is fighting off an onslaught of virtual physical drug representations similar or dissimilar to fighting off drugs in real life?
 - How are scores earned in a recovery game similar to measures of recovery in real life?
 - What are the ways that “health” in real life can be increased or decreased in relation to life encounters and environmental interactions?
 - How is the way the game lets you gain powers with success and lose powers with failure mimic real-life? Does positivity build more positivity, health build more health and vice versa?
- How does the productive recollection of or recounting of historical “war stories” of previous drug use contrast with current recovery efforts, redirecting the individual or group away from dwelling too much on the historical glorification of drugs and drug culture
- Using game play as an opportunity for empowerment and promoting self-efficacy –
 - encouraging successful game play effort, and discussing as a model of real-life determination in pursuit of a healthy goal
 - overcoming discouragement at unsuccessful play, and discussing as a model of real-life response and determination despite adversity

This process of manual writing will proceed throughout Year 1, and will be an iterative process of successive drafts as the game is expanded, revised and refined. As counselors become more familiar with the game, we will use drafts of the manual to train them in the principles of therapeutic game facilitation and progressively ask them to participate as facilitators.

A crystallized working draft will be the end product of this Aim. We will use the crystallized working version of the manual to train counselors for the pilot in Aim 2c and for the RCT in Aim 3

B.2.2. Work plan for Aim #2b – counselor feedback

As the game development in Aim 1 yields progressively playable prototypes, we will expose counselors from MMTC to the game and to patients playing the game to get their feedback. Counselors will be part of the four (4) patient focus group sessions in Aim 1, and their observations and feedback will be used to inform the iterative process of game design and development. As counselors become more familiar with the game, we will encourage them to practice the principles of therapeutic game facilitation and test new approaches through collaboration and improvisation. This iterative process will inform the manual writing in Aim 2a. As the manual writing in Aim 2a yields progressively usable drafts we will incorporate them into the ongoing training and qualitative testing process, and elicit feedback on the manual itself.

Moreover, about ¾ of the way through the game development and manual writing processes, we will conduct more formal extended interviews with n=5 counselors who have been exposed to the game. For these interviews we will ask the counselors to read a draft of the manual and conduct an observed session of game supervision / facilitation with a group of patients as a testing exercise. These qualitative interviews will provide feedback on therapeutic game facilitation as well as the manual itself as a useful training tool, all with an eye to what works and what doesn't from their professional counseling perspectives.

B.2.3 Work Plan for Aim #2c – small scale uncontrolled pilot

Using the game developed in Aim 1, the manual developed in Aim 2a, and incorporating the feedback gleaned in Aim 2b, we will conduct a small-scale uncontrolled pilot test of the procedures for the RCT to be conducted in Aim 3. The overall plan will be to conduct 2 small groups (n=5), one in each setting (in-patient and out-patient) to pilot the active game play intervention. Our objective is to test the logistics of the RCT implementation in both the in-patient and out-patient setting in order to establish and refine realistic standard operating procedures for the trial. This will give us a clearer picture of the concrete logistics involved in scaling up from intermittent testing with smaller numbers to the routine of a clinical trial with larger numbers. We will test a variety of practical issues, such as: recruitment, patient flow, interaction with the daily life of a busy clinical operation, timing of assessments, timing of game play in relation to other patient activities, scheduling of game play in both the inpatient and outpatient settings, security of game equipment, subject tracking and follow up etc.

We will train the counselors in therapeutic game facilitation using the manual, recruit subjects for the uncontrolled pilot, then run these 10 subjects through the game play intervention using the protocol for the clinical trial. This process should take about 4-6 weeks at the beginning of year 2. This pilot will give us vital information about feasibility and acceptability, and will allow any necessary last minute modification and fine-tuning of the details of the SOP's for the trial before the actual trial begins. If there are any substantial changes in the protocol based on the pilot, then we will not utilize the outcome data from the pilot subjects in the analyses for Aim 3.

B.3. Work Plan for Aim #3: Efficacy Study

Goal: To conduct an evaluation of Recovery Warrior 2.0 with youth in recovery (N=100) to assess the impact of the game on relapse-related outcomes. Participants in inpatient treatment will be randomized to game play or treatment as usual. Those randomized to game play will be exposed to the game four times per week (4x/wk) for 1-2 weeks as inpatients and then weekly for 4 weeks as outpatients. All participants will be assessed at baseline, and followed up in-person or by phone prior to discharge from inpatient treatment (approximately 2 weeks), and 4, and 12 weeks. Outcomes will be assessed comparing those randomized to game play and those randomized to treatment as usual. The gameplay will be conducted at MMTC, and the data analysis will be conducted mainly at Dr. Abroms office, with some performed at MMTC and at Media Rez.

B.3.1. Overview of Testing for Aim #3

The goal of Aim 4 is to conduct an evaluation of the Recovery Warrior prototype 2.0 in the context of adolescents in inpatient and outpatient recovery. The study for the evaluation will consist of a study of the mediators of relapse (Hypothesis 1), treatment adherence/retention (Hypothesis 2), and drug use outcomes (Hypothesis 3) among adolescents recruited from the opiate addiction program at Mountain Manor Treatment Center in Baltimore, MD. The testing will be supervised by Dr. Abroms, with support from Mr. Greenberg and Dr. Fishman, along with the team at Mountain Manor Treatment Center

B.3.2. Overview of Recovery Warrior Game Play Intervention

B.3.3. Sample and Recruitment:

Subjects will be recruited from opioid addicted patients age 15-24 admitted for inpatient treatment at MMTC. Approximately 16-18 such patients per month are admitted to MMTC. We estimate that 60-70% or 10-13 per month will consent to participate in the study. We expect that the enrollment as a percentage of eligible patients will be higher than is sometimes typical of clinical trials as the patients will already be engaged in treatment, and will be offered a fun intervention with relatively small research burden. Thus we anticipate we will recruit 100 subjects over 8-9 months.

Patients will be approached by MMTC staff within their first few days of admission, allowing some time for adjustment to the inpatient environment and resolution of the most acute phase of withdrawal distress. Patients will be assessed for eligibility. To be eligible for inclusion in this study, a patient must be: 1) enrolled in inpatient treatment for opiate addiction at MMTC, 2) 15-24 years old, 3) an English speaker, 4) without a debilitating co-morbid psychiatric condition that would make participation unsafe (e.g. acute suicidality, unstable psychosis), and 5) not pregnant (because of the physical exertion required to play the game). For Patients under the age of 18 we will obtain assent as well as parental consent.

Those that give informed consent will begin game play during week 1 of inpatient treatment and continue through discharge from inpatient treatment. All participants discharged from inpatient treatment will be offered outpatient care at MMTC. Of those discharged from inpatient treatment, approximately 70% or 10 per month will choose to continue treatment as outpatients at MMTC (while others will continue care at other outpatient centers or choose to forgo outpatient care). Youth that continue outpatient care at MMTC will continue their game intervention exposure (or TAU) for an additional 4 weeks during outpatient treatment. Those youth that choose to not enroll in outpatient treatment at MMTC will be followed for outcomes without further opportunity for game intervention exposure.

B.3.4. Procedures:

Adolescents and young adults who provide informed consent will be enrolled in the study from the inpatient unit. Eligible individuals will be approached on their second to third day of inpatient care and given the opportunity to enroll in the study. For those interested, they will be consented by Mountain Manor research staff and given a baseline interview. For those randomized to game play, participants will be given the opportunity to play the recovery warrior game with a Mountain Manor counselor supervising the game play on a 4x/wk basis for the length of their stay in the in-patient unit (The estimated length of game play (following study enrollment (admission day +2)) is based on usual treatment protocol is 8 days of game play). Each 1-hour session will include an introduction to the game by the counselor (5 min), at least 20 minutes of game play for 3-5 participants in a multi-player format. Participants will be interviewed at discharge from outpatient (approximately 2 weeks after enrollment), as well as at 4, and 12 weeks, post enrollment. Follow-up interviews will be conducted by phone or in-person at 2, 4, and 12 weeks. See Table 1 below for measures.

B.3.5. Measures and Analysis

Data for the evaluation will come from the baseline and 4, and 12 weeks surveys. See Table 1 for an overview of measures. Standard measures will be used for opiate use. Opiate use will be defined as self-report of opiate use in the past 7 days which will be verified for participants continuing care at MMTC with urine analysis. The follow-up surveys for both groups will consist of a repeat of the baseline survey with the exception of the demographic and opiate history items. For those randomized to game play, additional questions will assess the participant's satisfaction with game play.

Additionally, at 4 weeks, measures of user engagement in Recovery Warrior will be collected through a retrospective review of the computer records from game play. The system will record each time a user

plays the game, including minutes of game play and score received. For each participant, the number of total minutes of game play will be calculated across the intervention period and total score and achievements on the game will be assessed.

Table 1. Measures			
	Baseline	Outpatient discharge 2 weeks, 4 weeks	12 weeks
Demographics	x		
Drug History	x		
Self-report on Drug Use (past week; past 30 days)		X	x
Satisfaction with recovery warrior (Rimer et al. 1994)		X	x
Self-Efficacy for Refusal (Hecht et al. 2009)	x	X	x
Cravings (Flannery et al. 1999)	x	X	x
Attendance rates/Drop-out rates		X	x
AES/SAES craving rating (Likert and visual analog)	x	X	x
Working Alliance Inventory— Short Form (WAI) (Garner,2008; Horvath,1989; Tracey,1989)	x	X	x
Self-reported abstinence Urine drug screens for opioids, oxycodone, other drugs	x	X	x
Suggestions for improvement		X	x

Abstinence will be measured with self-reported measures of abstinence in the last 7 and 30 days. This outcome will later be biochemically-confirmed through laboratory urinalysis that occurred as part of routine care at MMTC using stand EMIT technology. The 5-item, 7-point Penn Alcohol Craving Scale (PACS) (Flannery et al. 1999) will be altered to apply to opiate use and used to assess the intensity of a participant's cravings (0=none at all; 6=very strong). Two scales will be used to assess participant self-efficacy in ability to refuse offers of opiates and to resist opiate use in a variety of scenarios. The first is the Marijuana Resistance Self-Efficacy (MRSE) scale (Hecht et al. 2009; Pettigrew et al. 2011), which will be adapted for opiate use. It will use a 4-item, 4-point scale (1= very easy; 4= very hard) that asks how easy or hard it would be to refuse opiates if offered, explain why you didn't want to use, avoid the situation in the first place, and leave the situation. In addition, the Cannabis Refusal Self-Efficacy Questionnaire (CRSEQ) (Young et al. 2012) will also be used and adapted for opiate use. It uses 14-items, 5-points (1= very sure could not resist; 5= very sure could resist) to assess participant's confidence in their ability to resist using opiates in a variety of potential trigger situations. Examples of such situations include when they are angry, bored or upset, or when they know their friends are using. Treatment view measures, such as level of enjoyment, progress and satisfaction with current services, including the Counselor Alliance Scale (CAS), which was taken from the Working Alliance Inventory (Garner, 2008; Horvath, 1989; Tracey, 1989), will also asked on surveys. CAS uses 7-items; 7-points to measure how well participants believe staff is working with them to improve their situation (1=Never; 7=Always). Satisfaction with the game will be asked with open-ended questions about what participants may have learned, liked and not liked about the game and a question about how they would change the game to improve it (Rimer et al. 1994).

Attrition. Sample attrition is a significant concern in longitudinal studies, especially with drug abusing populations. We plan to prevent attrition by: 1) communicating with participants through telephone, mail and text messaging; 2) collecting the names and number of two contacts in the event that we can't reach a participant through his/her own contact information, 3) offering cash incentives for assessments; and 4) making up missed assessment interviews. Differential attrition between conditions is also a concern. Because the participants in the game play condition will receive additional points of contact during the intervention compared with the TAU condition, participants in the game play condition may be more inclined to participate in measurement activities. Furthermore, we hope to minimize differential loss-to-follow-up between those who relapse and don't relapse by emphasizing payment for follow-up surveys will be offered regardless of abstinence. We believe that it will be reasonable to assume 30% loss to follow up by 8 weeks, so for the primary outcomes of the study we will have 70 participants or about 35 participants in each condition.

Quality Assurance. Mechanisms to ensure quality in data collection and analysis will include a detailed procedure manual, intensive training of study staff including, close supervision by the investigator, use of standardized forms, systematic review of assessment instruments, review of random assignments, and consistency checks of data.

B.3.5 IRB Review Process

We will obtain IRB clearance for the evaluation using a commercial IRB and anticipate a full committee review. The study will be reviewed annually by the IRB, including review of any adverse event reports that may occur (The PI will notify NIH of any adverse events immediately should they occur). Rare adverse events may include respondent distress or confidentiality breaches.

B.3.6 Analysis

Outcomes will be determined by comparing intervention and control groups. We will conduct an intent to treat analysis and participants who are lost to follow up will be treated as non-abstainers in all outcome analyses. Prior to performing the outcome analysis, we will examine the reliability of scales and check for normality of distribution in continuous variables. We will also examine the extent to which preexisting differences exist between groups on both the dependent and independent variables at baseline. Because of randomization, we expect minimal differences in baseline characteristics between the two groups. In addition, the level of response at follow-up will be compared across the groups to assess whether there was a differential loss to follow-up among the two groups.

The following specific hypotheses will be analyzed:

Hypothesis 1: Participants who receive Recovery Warrior 2.0 will report greater improvements in the mediators of addiction recovery (e.g. fewer cravings, greater improvements in refusal self-efficacy,) compared to those in usual care.

Hypothesis 2: Participants who receive Recovery Warrior 2.0 will have higher ratings of their overall treatment program at Mountain Manor and better treatment adherence (e.g. higher rates of inpatients completion, higher rates of linkage to outpatient care, better improvements in attendance in outpatient clinics, higher levels of counselor and treatment alliance, and lower drop-out rates) compared to those in usual care.

Hypothesis 3: Participants who receive Recovery Warrior 2.0 will have better positive outcomes on clinical relapse measures (e.g. self-report of drug use, urine drug screens) compared with those in treatment as usual.

Opioid clinic retention

n=134

retention

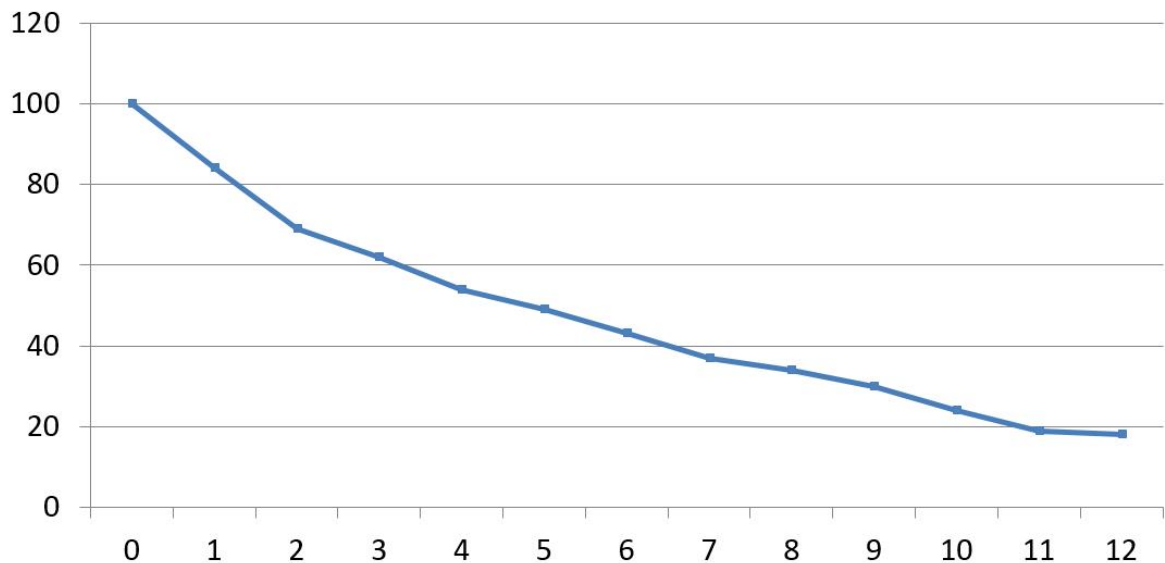


Figure 1. Historical retention in outpatient treatment

Research Question 1: Does playing Recovery Warrior result in improvements in the mediators of relapse compared with the TAU group?

As noted in Figure 2, several cognitive constructs, as postulated by the Social Cognitive Theory (SCT) (Bandura 1986) are predictive of whether an adolescent will relapse. An analysis of cognitive determinants is important because it will provide an indicator of whether the program is likely to have an effect and will explain the mechanism by which the program is likely to have an effect. Among SCT constructs, self-efficacy, or the belief in one's own ability to quit, has been shown to be highly predictive of relapse (Godin et al. 1993; Woodby et al. 1999). Additionally, intensity of cravings has been demonstrated to be an important predictor of relapse.

We will test the effect of Recovery Warrior on improvements in levels of cravings and other cognitive determinants of relapse such as self-efficacy. Using the five-item, six-point PACS (Flannery et al. 1999), modified for opiate cravings, we will examine changes in the levels of cravings between baseline and the 8 week follow-up and examine differences in changes between the game play and TAU groups using a t-test. Similar analyses will be conducted for other cognitive determinants of relapse including self-efficacy. Additionally, multiple linear regression will be used to determine whether individual factors (e.g. race/ethnicity, age etc.) are associated with changes in craving levels, and whether the intervention has an independent effect on craving levels when controlling for other factors. Similar analyses will be conducted for other cognitive determinants of relapse.

Research Question 2: Does playing Recovery Warrior result in higher ratings of their overall treatment program and higher adherence to outpatient treatment compared with the TAU group?

We will assess treatment and counselor alliance using the Working Alliance Inventory— Short Form (WAI) (Garner,2008; Horvath,1989; Tracey,1989). We will examine participants' overall levels of Counselor Alliance at baseline and compare with their scores at the end of follow-up (week 4). Our analysis will test the following main hypothesis: Participants randomized to game play will have higher overall scores on the treatment alliance inventories and greater improvements in scores on the alliance inventories compared to the TAU group. To test this hypothesis, we will use a one tailed test to examine whether the game play is associated with higher scores and greater improvements in scores. Additionally, multivariate linear regression will be conducted (with the outcome as the alliance inventory) to adjust for potential confounders and to identify the independent effects of covariates on alliance scores (e.g. self-efficacy, sex, age etc.). This will increase the statistical power for analysis of intervention effects and adjust for imbalances between the groups which may exist due to chance.

We will also examine dose of treatment in outpatient care. Addiction recovery interventions which are more intense (e.g. more time involved, more sessions) have been found to be more effective. One goal of the Recover Warrior program will be to promote treatment adherence, as operationalized as promoting linkage to outpatient care and preventing early drop out from outpatient care. Thus, we will investigate whether the game play condition leads to significantly longer attendance in outpatient care. For all participants, an index will be tabulated to measure total service use following discharge from inpatient care . We will measures the total number of outpatient sessions of treatment attended by participants at Mountain Manor or other treatment center by the time of the 8 week follow-up. Our analysis will test the following main hypothesis: Participants who are assigned to the game play condition will attend more outpatient sessions than those randomized to TAU. To test this hypothesis, we will use a *one* tailed test to examine whether the game play condition is associated with more outpatient sessions attended.

Research Question 3: Does playing Recovery Warrior result in better clinical outcomes than TAU?

A main-effects analysis will be conducted comparing relapse rates for those randomized to game play compared with TAU. The primary outcome of will be self-report of opiate use in the past 7 days at 12 weeks follow-up. Differences in the rates of drug use between the 2 groups will be examined with a 2 X 2 (Treatment Group X Drug use status) significance test. We will conduct an intent-to-treat analysis, where individuals who were not present for data collection will be assumed to be using opiates, as well as a traditional analysis using only data that is present. Other clinical outcomes will also be examined in a similar way. Additionally, multivariate logistic regression will be conducted to adjust for potential confounders and to identify the independent effects of covariates on relapse (e.g., self-efficacy, race/ethnicity, age etc.). This will increase the statistical power for analysis of intervention effects and adjust for imbalances between the groups which may exist due to chance. We will also examine urine drug screens using standard EMIT technology that measure for the presence of opioids, oxycodone, and other drugs for participants who continue care at MMTC. This will provide a way to biochemically confirm self-report of abstinence for a sub-sample of participants and provide a measure of the reliability of self-report.

B.3.7. Sample size/power

For Research Question 1 related to changes in craving levels between the two conditions, we hypothesize that the game play condition would have greater changes (improvements) in cravings than those in the TAU between enrollment and 8 weeks follow up. In the prior Phase 1 pilot study we conducted (no control group), we found that using the five-item, six-point PACS (Flannery et al. 1999) modified for opiate cravings, participants reported declines in cravings between week 1 (12.7; SD=8.4) and week 4 (9.8; SD=8.3). The average participant experienced a decline in their craving level of 2.4 points on the PACS scale. We hypothesize that improvements in cravings will be greater for the

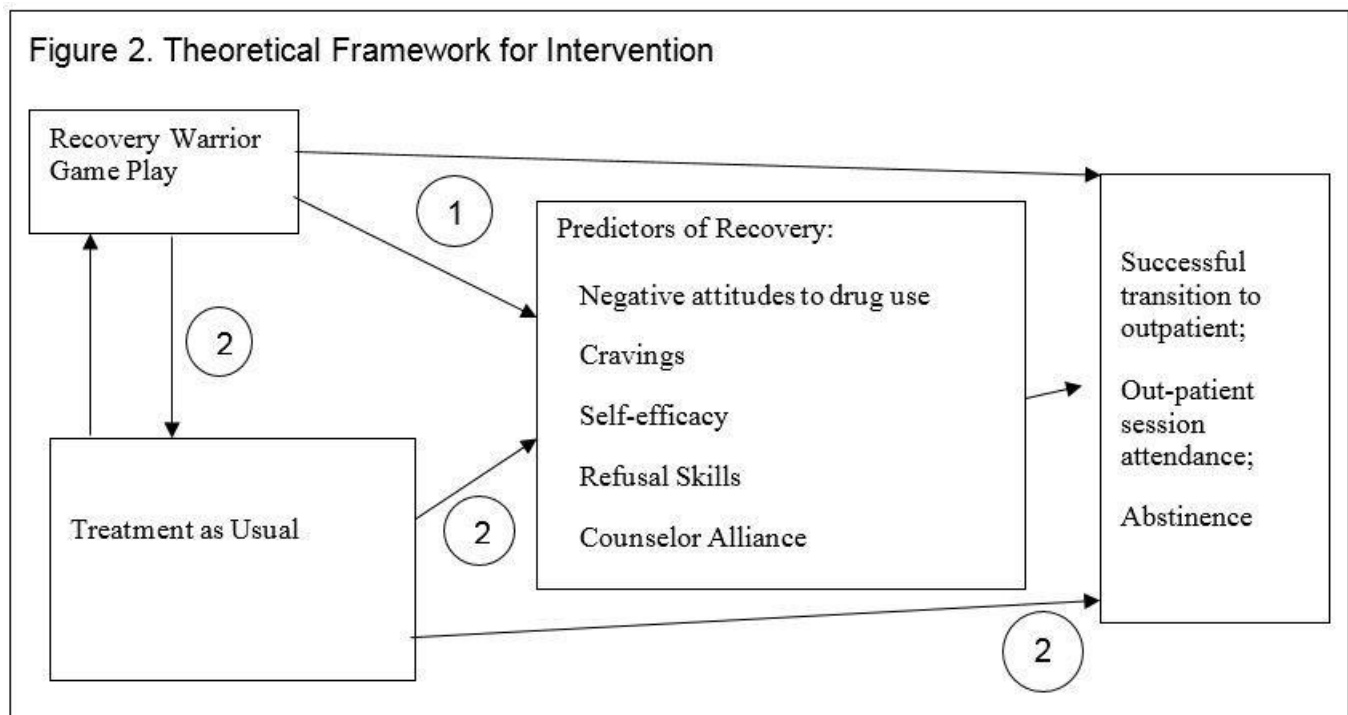
intervention group (game play) than the control group and. For a t-test comparing group means on the craving scale, there is 80% power to detect a standardized effect size of .53 between the two groups. This effect size is usually considered moderate in magnitude for social and behavior measures. Thus, for the current study, power calculations for testing differences between groups, we assume alpha = .05 (1-sided) and a 30% loss to follow-up rate, requiring a total of n=35 participants with complete data in each group. The actual power is likely to be higher for the multivariable models which control for baseline measures and covariates.

B.3.8. Potential pitfalls and alternative approaches:

The Mountain Manor Treatment Center in Baltimore, MD, will serve as our primary source of participants. Based on historical trends, we expect more than enough potential participants during the time frame of testing. However, if we face any difficulties recruiting from this clinic, we have made agreements with MMTC to recruit participants from their clinic in Rockville, MD. Media Rez will bear any additional costs in the unlikely event we need to recruit from this second facility, and will pay the additional personnel from company funds.

C. Theoretical Basis of Recovery Warrior

The development of Recovery Warrior will be based on the social cognitive theory (SCT) (Bandura, 1986)ⁱ within the framework of a biobehavioral addiction model. (See Figure 2). Game play will be aimed at improving self-efficacy, promoting negative attitudes to drug use, increasing perceived social support from the treatment facility, and providing refusal skills training. Based on the biobehavioral model and SCT, Recovery Warrior game play could impact opiate recovery in teens through a variety of pathways. We expect that Recovery Warrior could improve recovery by altering established predictors of quitting set forth by SCT (Figure 2, Pathway 1)(Abrams et al. 2003).ⁱⁱ Additionally, Recovery Warrior could affect recovery by increasing the use of additional treatment services (e.g. promoting attendance at sessions) (Pathway 2;) and thereby increase contact time (Fiore et al. 2000). Pathways 1 and 2 correspond to Hypotheses 2 and 3 in Aim 4 of the research project.



Examples of the theory-driven proposed mechanisms of the therapeutic effect of the Recovery Warrior game include improvements in:

Negative attitudes to drug use

- It is expected that gameplay, through ritualized battling and destruction of drug-associated icons, will reinforce the sense of drugs as “the enemy” and the adolescent’s identity as taking a crystallized stance in opposition to drugs

Social support

- It is expected that fun gameplay in the treatment setting will make treatment more engaging, and increase the sense of social support provided by the treatment program
- It is expected that fun gameplay will increase social support by reinforcing the use of prosocial recreational alternative to drug use
- It is expected that sharing fun gameplay with other peers in treatment, especially in multi-player game play, will promote a sense of a common therapeutic goals, prosocial connection to peers, and recovery-oriented social support

Self-efficacy

- it is expected that successful destruction of drug associated icons, reinforced by the inherent and very compelling reward schemes built into video games (points, unlocking new levels, competition, etc.) will promote self-efficacy in the adolescents sense of success in combating drugs in real life
- it is expected that the virtual transformation of fighting drugs, normally a very complex task in real life, fraught with ambivalence, into a simpler non-ambivalent task in fantasy, will generalize, and promote self-efficacy by helping to tip decisional balance, translated back from fantasy into real life
- it is expected that fantasy gameplay will help imbue the struggle to achieve recovery with an aura of heroism, promoting self-efficacy by reinforcing the role of the adolescent as the “Recovery Warrior”

Refusal Skills

- it is expected that certain features of gameplay will simulate critical components of refusal skills (conscious decision stance towards refusal, automatic unconscious decision stance towards refusal, vocalization of refusal, etc.), and that learning and rehearsal of those components through repetition in the game will strengthen refusal skills in real life

Treatment and Counselor Alliance

- it is expected that the counselor’s role in providing access to fun gameplay will generalize to an increase in the overall alliance with the counselor and treatment

D. Reports

REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: <http://www.vhhs.gov/web/508/index.html> under "Making Files Accessible." All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

Technical Reports

I. Quarterly Progress Reports

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first partial calendar month of performance beginning on the contract effective date. Thereafter, the reporting period shall consist of each calendar month. A Quarterly Report will not be due when a Final Report is due.

Quarterly Report 1: Summarizes the project start, the work of the technical team on the design document and on structuring the software architecture of the Phase II prototype. Details the IRB progress, the first focus test with counselors and the first focus test with the youth in the MMTC recovery program. Includes preliminary commercialization efforts. The analysis of the interviews with counselors and youth in treatment serves as the main portion of Report 1, and these recommendations for design changes will inform the further development and revision of the Recovery Warrior prototype in Aim 2. Based on the results of the concept testing, decisions will be made about content areas to focus on and how best to alter the design of the prototype.

Quarterly Reports 2-3: Describes the technical team progress in building out the core elements of the software architecture, summarizes feedback from the focus groups with counselors and youth in treatment, describes the process of incorporating feedback, includes samples of the counselor training manual in progress. Lists ongoing commercialization steps.

Quarterly Report 4: Summarizes the completed design document, lists the essential elements of the feature-locked final version of the Phase II prototype, describes the system to output formatted records of each player's performance, describes the feedback from the final focus group sessions with counselors and youth in treatment, and includes the main features of the final version of the counselor training manual. Lists ongoing commercialization steps.

Quarterly Reports 5-7

Details the process of recruitment, informed consent, inpatient testing, transition to outpatient testing, follow-up processes, and the results of ongoing testing. Lists the results of outreach efforts to treatment facilities to gauge interest in the product and other work on commercializing efforts. Also includes information on improvements to the commercial release version (not the Phase II test prototype, which has been feature-locked).

2. Final Report

The final report includes a summation of the work performed and results obtained for the entire contract period of performance. It provides comprehensive details of the results, innovation, and accomplishments achieved. It summarizes the collected data, describes the data analysis, explains the conclusions of each hypothesis, and whether they proved correct. It describes the state of the game design at the end of Phase II and lists the next steps in the commercialization process. It lists any changes made to the counselor training manual and summarizes the final version of it.

3. Prototype Video Demo

Part of the final report is a 5-minute or less "video demo" of the Phase II game, highlighting the main features and components, both on disc and in the form of an Internet link to the video for review. The video is 508 compliant, with Closed Captioning working.

- END OF STATEMENT OF WORK – END OF PUBLIC MATERIAL-

-START OF PROPRIETARY AND CONFIDENTIAL MATERIAL-

6. RESOURCES AND DIRECT COSTS

All facilities are in the United States, and all activities, both software production and research, will be performed in their entirety in the United States.

6.1: Facilities and Equipment

All facilities are in the United States, and all activities, both software production and research, will be performed in their entirety in the United States.

Media Rez Facilities: Media Rez has the facilities and equipment to build professional quality software, apps, and video games, including games using Microsoft's Xbox Kinect motion and voice sensor. Media Rez is a software production office and research lab at 1325 Corcoran St. NW Washington DC, 20009. The office is a 10 minute drive from Dr. Lorien Abrams' office. Work at Media Rez is dedicated to software development on multiple platforms, including PC, game console, smartphones, handheld, Web, and cloud applications. It is located about 35 miles from Mountain Manor Treatment Center and about a mile and a half from Dr. Abrams office, making in-person visits relatively easy.

Equipment

The office is outfitted with software development workstations and game consoles including Kinect hardware for development and game testing; has a recording studio for game voiceovers and Foley; and standard office equipment like high speed Internet, printers, scanners, etc. In-house equipment at Media Rez that is relevant to the performance of the proposed contract include three software development workstations equipped with the following: a) the latest version of **Unity 3D v4.3** along with license and numerous Unity assets from the Unity Asset Store including Playmaker, b) **Microsoft's Xbox 360 Software Design Kit (XDK)** with compiler, source libraries, and tools required for Xbox 360 development along with **Microsoft Visual Studio**, integrated with the XDK; c) **Kinect** motion sensing hardware; d) the latest version of **Kinect for Windows Software Development Kit (SDK v1.8)**; e) the latest version of the **Microsoft XNA Game Studio 4.0** programming environment for game development based on the Microsoft .NET Framework, f) the latest version of the **DirectX Software Development Kit (SDK)**, along with many other software tools and code libraries. **XNA Game Studio 4.0 in the Windows Phone Developer Tools.** Other hardware includes professional quality digital recording gear including **Creative Labs X-Fi Elite Pro** with professional grade digital-to-analog (DAC) conversion, **AKG Pro Vocal** microphones, and pro-level headphones from **Sennheiser and Shure**. Our lab has virtual reality headsets, including the high-end **eMagin VR Headset** used in the Girard, et al. pilot study, "Crushing Virtual Cigarettes Reduces Tobacco Addiction and Treatment Discontinuation," which we used in feasibility testing prior to Phase I to compare the experience of using it to the experience of using the Kinect. The Media Rez office also has a suite of game production software like the **Autodesk Entertainment Creation Suite, Adobe Photoshop, Adobe Premiere**, a software and hardware test lab with wide variety of tech equipment, a reference library of game development books and magazines, many volumes of proceedings from the Game Developers Conference, and hundreds of reference video games. Among our development tools are extensive libraries of custom programming code built up over more than twenty years of software and video game development. These include specific game development tools like 3D graphics rendering, artificial intelligence routines for life-like character behaviors, and audio/video compression. We also have large databases of 3D art models, art textures for use on the 3D models, animations, sound effects, etc. for use in games. These make the creation of in-game assets much easier than creating everything from scratch each time a new asset is needed.

Mountain Manor Treatment Center (MMTC)

Testing Facilities: The performance site for the testing of the game will be Mountain Manor Treatment Center (MMTC) in Baltimore, where Co-Investigator Dr. Marc Fishman, serves as Medical Director and where the adolescent test subjects receive clinical treatment. It is about 35 miles from the Media Rez offices and Dr. Abrams' office. This relatively close proximity worked well for Phase I testing. The facilities will be available for all testing proposed under Phase II.

MMTC, a division of Maryland Treatment Centers (MTC), will be the site of the proposed pilot study. It offers a broad continuum of care for drug-dependent and dual diagnosed youth which includes detoxification, buprenorphine maintenance, acute short-term residential treatment, medium-term residential treatment, partial hospitalization program (PHP), intensive outpatient treatment (IOP), and outpatient treatment, including an integrated mental health clinic (see Fishman, 2003; Clemmey, 2003). Of note MMTC has a specialty clinical program for the treatment of youth with opioid addiction, which will serve as the target population for the testing of the game. MMTC is located on a 14-acre campus at 3800 Frederick Ave, Baltimore MD 21229. Its large (60,000 square foot) facilities include all things necessary for the operation of a high volume inpatient and outpatient treatment center and administrative headquarters, including residential and outpatient treatment space, residential treatment living quarters, offices, medical treatment space, full commercial kitchen, computer network, private exam rooms and nursing station for dispensing medications. MMTC has a full infrastructure to manage clinical and research activities including administrative, business office and billing, utilization management, Information Technology, Quality Assurance, Human Resources, clinical leadership and supervision, on-site training, facilities management and support services.

MMTC is well suited as the clinical facility to carry out the proposed project, with extensive resources matched to the anticipated testing, including: a well-established flow of adolescent and young adult patients with opioid dependence through a full continuum of care; the availability of trained counselors and therapists; current active capacity for buprenorphine treatment; routine access to laboratory services; on-site medical evaluation and treatment capacity; routine nursing personnel and service; routine 24-hr on-call medical and psychiatric emergency systems; routine policies and procedures and regulatory compliance QA for medication storage and medication administration; and an institutional culture accustomed and receptive to treatment innovation and research.

MMTC has an established track record of successful collaboration in clinical research including the CTN adolescent Buprenorphine study (CTN 0010) and OROS-MPH (Concerta) trials. MMTC is collaborating with Friends Research Institute and the University of Pennsylvania (C. O'Brien [Lead PI]) in a multi-site study of extended release naltrexone for adult probationers. MMTC served as a site in the recent NIDA sponsored trial of vigabatrin for cocaine dependence, and is about to begin as a site in the NIDA multi-site trial of nopicastat for cocaine dependence. MMTC has a history of innovation in applications of technology to treatment. For example we have recently received a fundable score on a collaborative project to use a computer-assisted cognitive rehabilitation intervention to augment counseling treatment for adolescent marijuana users.

MMTC is a JCAHO accredited community provider in Baltimore and has a long history of successfully treating the "toughest" cases, those adolescents with very high severity drug use who are refractory to numerous previous treatment interventions. MMTC's residential program treats approximately 700 adolescents and young adults addiction patients annually, while the outpatient programs serve over 500 adolescents annually. MMTC also has a long tradition of clinical teaching. It serves as a training site for the addiction rotation for Johns Hopkins Child Psychiatry fellows, for research and clinical electives for the Hopkins general Psychiatry residents, for the adolescent rotation for University of Maryland Addiction Psychiatry fellows, for Hopkins Pediatric residents during their adolescent medicine rotations, for Hopkins Adolescent Medicine Fellows, for social work interns for University of Maryland, and for psychology extern practicum placements for Argosy University.

Laboratory:

Urinalysis testing: MMTC uses the commercial laboratory Dominion Labs for its urine drug testing. Samples are routinely collected with staff supervision. Samples are picked up daily by UPS and delivered to the lab. Quantitative results are reported with standard thresholds using the EMIT system (enzyme multiplied immunoassay test) with an automated urine testing system.

Blood testing: MMTC has a phlebotomist available daily. It uses the commercial laboratory Dominion Diagnostics for its testing. Samples are picked up daily by UPS and delivered to the lab. Results are reported through a web based system.

Clinical

Clinical treatment for adolescent and young adult patients with opioid dependence will be conducted at MMTC. Subjects will be recruited through MMTC's high volume on-site clinical continuum, which routinely provides a full range of services including detoxification, acute short-term residential treatment, medium-term residential treatment, partial hospitalization program (PHP), intensive outpatient treatment (IOP), and outpatient treatment, including an integrated mental health clinic. MMTC has numerous office spaces and group rooms suitable for the provision of the individual and group counseling, as well as treatment and exam rooms for medication administration, evaluation and observation. Secure medication storage facilities are available with standard double locked cabinets, and standard medication log reporting.

Computer

MMTC has a computer network currently in operation for data collection, data management, word processing, and on-line interviewing. There is a seamless broadband access to internet services. This permits direct computer entry at the time of collection of all assessment data, and facilitates data entry and review prior to analysis.

Office and Game Testing Space

Adequate space and office facilities are available at MMTC for this project. A testing room will be available in close proximity to the clinical program space where several gaming consoles can be set up and run simultaneously with enough space for observation, debriefing, discussion and interviewing. Secure locked storage space is available for protection of equipment between uses. The office of Dr. Fishman (PI) is on the 1st floor of MMTC in close proximity to the outpatient clinical treatment area and in close proximity to the MMTC offices that will be used by the research staff on-site.